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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,600	05/23/2001	Virginia Smith-Swintosky	JJPR-0014 (ORT-1436)	9298

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EXAMINER	
MOHAMED, ABDEL A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/863,600	SMITH-SWINTOSKY ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/2/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER ALLOWANCE OR QUAYLE ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 06/02/06 has been entered.

AKNOWLEDGEMENT OF INFORMATION DISCLOSURE STATEMENT AND THE STATUS OF THE CLAIMS

2. The information disclosure statement (IDS) and Form PTO-1449 filed 06/02/06 is acknowledged, entered and considered. However, references cited as U.S Patent Nos. 5,773,569 and 5,830,851 are not considered and initialed because they were considered earlier (See e.g., Paper No. 23). With respect to the complaint and amended complaint of the litigation between an assignee of the present application No. 09/863,600 ('600 application), Ortho-McNeil Pharmaceutical, Inc., and Affymax, Inc., case No. 04CV6216 in the United States District Court fro Northern District of Illinois, Eastern Division have been considered and entered. It is noted that Applicant has stated that Affymax has dropped all of the allegations of incorrect inventorship and

ownership with respect to any claim in the '600 application. However, in regard to the ongoing nature of the litigation, the response to this Office action must include the litigation status. Claims 55-58 are now pending in the application.

CLAIMS REJECTION-35 U.S.C. § 102(b)

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 55 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Weiss et al (U.S. Patent No. 6,165,783).

The instantly claimed invention as drafted in claims 55 and 56 are broadly directed to a method for promoting neurite outgrowth in a cell culture (i.e., any cell culture which is not defined, and as such would read on EPO), comprising administering to said cell culture an effective amount of a peptide **comprising** one or more monomeric peptides, wherein each of said monomeric peptides comprises a sequence independently selected from SEQ ID NO:8; SEQ ID NO:19; SEQ ID NO:20; SEQ ID NO:21; SEQ ID NO:17. The prior art of Weiss et al ('783 patent) discloses a method of producing neurons or neuronal progenitor cells which can be used for transplantation or other purposes, wherein the method comprises inducing multipotent neural stem cells to produce neuronal progenitor by proliferating the multipotent neural stem cells in the

presence of growth factor and erythropoietin (See e.g., abstract and summary of the invention). On column 4, the '783 patent states that it has been found that EPO, a hormone thought to influence the differentiative pathway of hematopoietic stem cells and/or their progeny, can increase the number of neuronal progeny that are generated from proliferated multipotent neural stem cells. Multipotent neural stem cells proliferated in the presence of EPO produce a greater percentage of neuronal progenitor cells than multipotent neural stem cells proliferated in the absence of EPO.

Further, as admittedly acknowledged on page 2, lines 22-26 in the instant specification, EPO influences neuronal stem cells, likely during embryonic development, and possibly during *in vitro* experiments of differentiation. Thus, clearly showing that EPO causes neurite outgrowth by committing neuronal stem cells to differentiate into neurons, while simultaneously acting as a neuroprotective function for existing neurons (See also, page 3, last paragraph of the instant specification).

Furthermore, on col. 5, lines 50-58, the '783 patent states that alternatively, a patient's endogenous multipotent neural stem cells could be induced to proliferate *in situ* to produce neuronal progenitor cells by administering to the patient a composition comprising one or more growth factors which induces the patient's neural stem cells to proliferate and EPO which instructs the proliferating neural stem cells to produce neuronal progenitor cells which eventually differentiate into neurons, and Example 3 shows erythropoietin-induced neurogenesis. Therefore, in view of claims language "**comprising**" which would not exclude EPO or other peptides comprising one or more monomeric peptides, the prior art teachings clearly encompasses the EPO fragments

claimed as SEQ ID NO:8; SEQ ID NO:19; SEQ ID NO:20; SEQ ID NO:21; SEQ ID NO:17, in the absence of evidence to the contrary the EPO-mediated neurogenesis and method for promoting neurite outgrowth in cell culture thereof as disclosed by the prior art anticipate claims 55 and 56 as drafted.

CLAIMS REJECTION-35 U.S.C. § 103(a)

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al (U.S. Patent No. 6,165,783) taken with Sakanaka et al (Proc. Natl. Acad. Sci. USA, Vol. 95, pp. 4735-4640, April 1998).

The prior art of Weiss et al ('783 patent) as discussed above discloses a method of producing neurons or neuronal progenitor cells which can be used for transplantation or other purposes, wherein the method comprises inducing multipotent neural stem cells to produce neuronal progenitor by proliferating the multipotent neural stem cells in the presence of growth factor and erythropoietin (See e.g., abstract and summary of the invention). On column 4, the '783 patent states that it has been found that EPO, a hormone thought to influence the differentiative pathway of hematopoietic stem cells and/or their progeny, can increase the number of neuronal progeny that are generated from proliferated multipotent neural stem cells. Multipotent neural stem cells proliferated in the presence of EPO produce a greater percentage of neuronal progenitor cells than multipotent neural stem cells proliferated in the absence of EPO.

Further, as admittedly acknowledged on page 2, lines 22-26 in the instant specification, EPO influences neuronal stem cells, likely during embryonic development, and possibly during *in vitro* experiments of differentiation. Thus, clearly showing that EPO causes neurite outgrowth by committing neuronal stem cells to differentiate into neurons, while simultaneously acting as a neuroprotective function for existing neurons (See also, page 3, last paragraph of the instant specification).

It is noted that the '783 patent does not mention that the cell culture comprises cortical cells or hippocampal cells as claimed in claims 57 and 58, respectively.

Although, the '783 patent discloses methods for the production of neurons or neuronal progenitor cells wherein multipotent neural stem cells are proliferated in the presence of growth factor and EPO which induces the generation of neuronal progenitor cells. The EPO may be exogenously applied to the multipotent neural stem cells, or alternatively, the cells can be subjected to hypoxic insult, which induces the cells to express EPO (See e.g. abstract). However, the secondary reference of Sakanaka et al on page 4636, right column, under the heading of Culture of neurons clearly shows the culturing of hippcampal and cerebral cortical neurons from brain of 19-day old fetal Wistar rats. Thus, since the secondary reference teaches the culturing of cortical and hippocampal cells for the intended purposes of neuroprotection which would result in promoting neurite outgrowth in cell culture. One of ordinary skill in the art at the time the invention was made would have bee motivated to adapt the above scheme of culturing hippocampal and cerebral cortical neurons cells wherein these cells have been demonstrated for neuroprotection purposes in the primary references of '783 patent because the '783 patent clearly shows that EPO is capable of promoting neurite outgrowth in cells since EPO has a neurotrophic activity.

Therefore, in view of the above and in view of the combined teachings of the prior art, the prior art makes *prima facie* obvious claims 57 and 58 at the time the invention was made for a method of promoting neurite outgrowth in a cell culture wherein the cell culture comprises cortical cell or hippocampal cells, absent of objective factual evidence or unexpected results to the contrary.

CONCLUSION AND FUTURE CORRESPONDANCE

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on (571) 272 0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JON WEBER
SUPERVISORY PATENT EXAMINER

Mohamed/AAM
August 9, 2006